protocols required to be followed and the manner in which studies need to be conducted including the ethical norms.

Since data on bioavailability/bioequivalence is required to be furnished along with application for approval of New Drugs as per Schedule Y of the Drugs and Cosmetics Rules, the facilities and expertise available with such centres/ laboratories is now being ascertained through experts, and on satisfactory reports, such centres are being approved for the purpose of acceptance of bioequivalence studies conducted by them.

Normally, bioavailability studies are being conducted by the departments of pharmacology in major medical institutions, some pharmacy colleges, in-house R&D centres of few pharma industry and private research laboratories.

Guidelines about the infrastructural requirements and working norms for bioequivalence studies are under preparation for consideration of the Drug Technical Advisory Board (DTAB). Steps are also being taken to assess the laboratories/centres which have been conducting these studies since earlier period.

Treatment and rehabilitation of HIV infected children

† 2157. SHRI DEVI PRASAD SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the information given in a press conference on 1st November, 2001 by Delhi Branch of Indian Academy of Paediatrics, in which it has been stated (that about two hundred children get infected by HIV in the country everyday, whereas more than eleven thousand children die due to this disease every year; and

(b) if so, the details of efforts being made by Government for the treatment and rehabilitation of such children?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR): (a) Yes, Sir. The estimates stated regarding the number of children infected every day with HIV are exaggerated. The estimated number of HIV infected children born in the country is approximately 30,000 per year with an HIV prevalence rate of 0.3% among pregnant mothers.

† Original notice of the question was received in Hindi.

(b) The children are being provided with treatment for opportunistic infections in Government hospitals. The family members and Community based organizations are encouraged to take care of AIDS orphaned children. The Government of India had initiated a feasibility study for AZT (Zidovudine) intervention to reduce Mother to Child Transmission in India at eleven centres vizMaharashtra(5), Chennai(3), Karnataka(l), Andhra Pradesh(l) and Manipur(l). The results were encouraging. The second phase of feasibility using single
dose Nevirapine has been started on 1st October, 2001.

Central clearance for importing certain Drugs

2158. SHRI RAMACHANDRA KHUNTIA:—Will the Minister of HEALTH AND FAMILY WELFARE be pleased to stale:

(a)whether Government propose to make it mandatory for researchers to obtain Central clearance for importing drugs meant for trial on human beings;

(b)if so, the details thereof;

(c)if not, the reasons therefor, and

(d)by when this proposal is likely to be implemented?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR) : (a) to (d) Drugs and Cosmetics Rule 122 is being amended with regard to New Drug clinical trials in the country. Investigators/Researchers will have to obtain Clearance from Drugs Controller General (India) to initiate clinical trials on human beings. This proposal is likely to be implemented during the current year.

Setting up of PHCs in U.P.

2159. DR. SWAMI SAKSHIJI MAHARAJ: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a)the areas in U.P. which qualify for setting up of PHCs but are without the same; and

(b)the steps being taken to set-up PHCs there?